DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region m2957n

Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

Telephone (973) 526-6006

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

September 2, 1999

Mr. Bragi Henningsson
President
North Landing Corporation
610 Brighten Road
Clifton, NJ 07012

File No: 99-NWJ-34

Dear Mr. Henningsson:

On March 29, 30, and April 4, 1999, an investigator from the Food and Drug Administration conducted an inspection of your seafood processing facility. The inspection was conducted to determine compliance with FDA's seafood processing regulations ((Title 21 of the Code of Federal Regulations Part 123(21 CFR Part 123)) and the Good Manufacturing Practice requirements for foods (21 CFR Part 110). The inspection documented deficiencies which cause seafood products processed by your firm to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act) and 21 CFR Part 123.

1) Your firm did not implement an adequate Hazard Analysis Critical Control Point (HACCP) plan for fresh tuna. This failure includes deviations from 21 CFR 123.6(b); 21 CFR 123.6(c)(3); and 21 CFR 123.6(c)(7), as follows:

   a) The hazard of histamine is not controlled during storage nor were there any monitoring records for the temperature of your coolers.

   b) There were no monitoring records for the internal temperature of your fish at receiving, as required in your HACCP plan.

   c) An appropriate critical limit is not listed for the control of histamine at the receiving step.

2) Your firm does not have written product specifications for imported tuna, as required by 21 CFR 123.12(a)(2)(i).

3) The HACCP plan of the foreign processor, [redacted], that you maintain on file as an "affirmative step" under 21 CFR 123.12(a)(2)(ii)(D) is not adequate because it does not include a plan to control the potential histamine hazard for fresh tuna. This failure in the HACCP plan content is a deviation from the requirements of 21 CFR 123.6(b) & (c).

The above identified deviations are not intended to be an all inclusive list of deficiencies at your facility. It is your responsibility to ensure that all seafood products processed and distributed by your firm are in compliance with the Act and all requirements of the federal regulations.

You should take prompt measures to correct these deviations. Failure to promptly correct the deviations noted may result in regulatory action without further notice. Such action includes seizure and/or injunction. In addition, FDA will not issue any certificates for export of any of the seafood products processed at your facility until your firm is in full compliance with the seafood HACCP regulation.

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct these violations, including an explanation of each step taken to prevent their reoccurrence. Your response should include copies of any available documentation demonstrating that corrections have been made. If corrections cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Your written reply should be directed to Diane Boucher, Compliance Officer, FDA, 10 Waterview Blvd., 3rd floor, Parsippany, NJ 07054, telephone (973) 526-6006.

Sincerely,

Douglas I. Ellsworth
District Director
New Jersey District

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